



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply.

EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

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Office of Prevention, Pesticides
and
Toxic Substances

November 1, 1999

Memorandum

Subject: **Phosalone** (PC Code: 097701; DP Barcode: D260579). Anticipated Residue Estimates for Purposes of Dietary Exposure Refinement for Select Import Commodities

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The following document, prepared as part of the Preliminary Human Health Risk Assessment, estimates the anticipated residues (ARs) of phosalone on select commodities imported by the U.S. The ARs in this memorandum were generated for the purpose of dietary exposure refinement, and will be used within the Dietary Exposure Evaluation Model (DEEMTM) to evaluate the acute and chronic dietary exposure and risk of the U.S. population to phosalone for the imported food commodities of interest.

BACKGROUND

Regulatory Information

Phosalone [*O,O*-diethyl S-[(6-chloro-2-oxobenzoxazolin-3-yl)methyl] phosphorodithioate] is an organophosphate insecticide and acaricide for which U.S. registrations were voluntarily withdrawn in 1989 by the registrant, Rhône-Poulenc Ag Company (RPAC). The Agency proposed revoking tolerances for pesticides with no active registrations, including tolerances for residues of phosalone in/on plant and animal commodities (63 FR 3057, 1/21/98). However, in response to this proposal, RPAC requested that the Agency not revoke tolerances for phosalone residues in/on almonds, grapes, pome fruits (apples and pears), and stone fruits (apricots, cherries, peaches, and plums) so that these commodities could continue to be imported legally by the U.S. In the Final Rule published in the Federal Register of 10/26/98 (corrected 1/25/99), the Agency decided to maintain existing tolerances for residues of phosalone in/on the specified commodities while revoking the remaining phosalone tolerances under 40 CFR §180.263 and §186.4800.

Tolerances

Tolerances for phosalone residues are currently expressed in terms of phosalone *per se* in/on plant commodities [40 CFR §180.263]. The Metabolism Assessment Review Committee (MARC) determined that parent phosalone is the only residue of concern to be regulated in/on plants (Kristina EL-Attar 10/04/99). There are currently no tolerances for residues of phosalone in animal commodities and the Agency has determined that none are required to support the proposed uses of phosalone.

Codex Maximum Residue Limits

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for phosalone in/on various plant commodities (see *Guide to Codex Maximum Limits For Pesticide Residues*); there are no MRLs for animal commodities. Codex MRLs for phosalone are currently expressed in terms of the parent compound for plant commodities.

ANTICIPATED RESIDUES

Residue Data

ARs for phosalone were estimated using FDA Surveillance Monitoring data summarized from 1992-1998 for all commodities, except almonds and cherries. ARs for phosalone on almonds and cherries were calculated from field trial results due to the insufficiency of monitoring data from the FDA Surveillance Monitoring Program and the unavailability of monitoring data from

the USDA Pesticide Data Program (PDP)¹. The FDA Surveillance Monitoring data for peaches were translated to apricots and plums in accordance with HED SOP 99.3. In the instances where both FDA Surveillance Monitoring data and USDA PDP data were available for a particular commodity (i.e. apples, peaches, pears, and grapes), FDA data were selected over USDA PDP data due to the abundance of import samples analyzed originating from countries identified in MRID 44792004 with phosalone registrations. Although the number of analyzed samples originating from countries with phosalone registrations did not meet the usual “100-samples-analyzed criteria” preferred for statistical purposes, the fact that only samples from those countries were considered in generating the ARs for the commodities of interest was viewed as being highly representative of the residues expected for phosalone in the U.S. diet. The field trial data used for almonds and cherries plus the FDA Surveillance Monitoring data used for apples, apricots, grapes, peaches, pears, and plums are summarized in Table 1 (page 4).

Usage Information

The percent of almonds, apples (fresh+dried), apple juice, apricots (fresh+dried+pulp/prepared or preserved+kernel from peach, plum or other stone fruits), cherries (fresh sweet & tart varieties), grapes (fresh+juice+wine), raisins (fresh basis), peaches (fresh including nectarines), pears (fresh including quince + nesoi), and plums (fresh+dried on fresh basis) derived from countries possessing phosalone registrations was assessed using statistics submitted by RPAC quantifying the amount of each commodity available for U.S. consumption from both domestic and foreign sources (MRID 44792004). These statistics, which reflect U.S. production data from the USDA National Agricultural Statistics Service averaged from 1992-1996 plus U.S. import data from the U.S. Department of Commerce averaged from 1992-1996, were used to generate the values summarized in Table 2 (page 5). These numbers were approved by BEAD via e-mail correspondence with HED (Jihad Alsadek 10/06/99).

Method of Calculation for Chronic and Acute ARs

The information presented in Tables 1 and 2 were used to estimate the residues of phosalone anticipated on almonds, grapes, pome fruits (apples and pears), and stone fruits (apricots, cherries, peaches, and plums) available for U.S. consumption in the diet. The approach used to generate the chronic and acute ARs for the crops of interest is illustrated for almonds on page 6. A similar method was employed to calculate the residues of phosalone anticipated on the other

¹ The registrant submitted field trial data reflective of the almond use pattern contained in the French Good Agricultural Practices (GAP), which allows three applications of phosalone at 0.75 kg ai/ha/application totaling 2.25 kg ai/ha/season (1x the proposed EU GAP rate) with a 70-day pre-harvest interval (PHI). The field trial data were found adequate in terms of the number of trials conducted and the geographical locations represented provided that the Italian label for stone fruit, which includes almonds and reflects a 21-day PHI for almonds, be revised to agree with EU GAP.

The field trials conducted on cherries were reflective of the French GAP, which allows two applications of phosalone at 0.60 kg ai/ha/application totaling 1.20 kg ai/ha/season (1x the proposed EU GAP rate) with a 14-day PHI. The field trial data were found adequate in representing the EU usage pattern. No studies, however, were performed on cherries according to the Canadian GAP which permits a maximum use rate of 3.0 kg ai/ha/season (2.5x the proposed EU GAP rate). The Canadian MRL of 6.00 ppm for phosalone on cherries was used, therefore, to represent the residues of phosalone anticipated on cherries from Canada.

crops/commodities. One hundred percent crop treated was assumed in all cases. This was viewed as being conservative of the dietary exposure to phosalone since the market share of the pesticide was assumed to be 100% in the production of the exporting countries.

Table 1. Phosalone Residue Data

Crop	Commodity	Data Source ^a	Total Number of Samples	Total Number of Detects	Individual Residue Values of Detects (ppm)
Almonds	nutmeat	FT	3	1	0.048 ^e
Apples	fresh + dried/paste	FDA	88 ^b	5 ^c	0.140, 0.200, 0.087, 0.060, 0.200
	juice (includes juice from concentrates)	FDA	73 ^b	0 ^c	N/A
Apricot	Translated data from peaches				
Cherries	fresh (European)	FT	6	6	0.59, 0.38, 0.23, 0.35, 0.42, 0.25 ^e
	fresh (Canadian) ^d	MRL	6	6	6.00 (6)
Grapes	fresh + juice + wine	FDA	107 ^b	0 ^c	N/A
	raisins	FDA	37 ^b	1 ^c	0.420
Peaches (includes Nectarines)	fresh (includes preserves, frozen puree & topping/syrup)	FDA	59 ^b	1 ^c	0.130
Pears	fresh	FDA	86 ^b	0 ^c	N/A
Plums	Translated data from peaches				

^a FT=Field Trial data, FDA=FDA Surveillance Monitoring data (1992-1998), MRL=Maximum Residue Limit

^b These numbers represent the imported samples originating from countries identified with phosalone registrations that were analyzed by the FDA Surveillance Monitoring Program for phosalone.

^c These numbers represent the imported samples originating from countries identified with phosalone registrations found to contain detectable residues of phosalone.

^d The Canadian MRL of 6.00 ppm for phosalone on cherries was used to represent the residues of phosalone anticipated on cherries from Canada since the field trail data were not reflective of the Canadian use pattern. The numbers in this row were generated by considering the percent of cherries available for U.S. consumption from Canada relative to those from Europe.

^e These values represent average residue values based on replicate sample analysis.

Table 2. Phosalone Usage Information

Crop	Commodity	Total Available for U.S. Consumption from Domestic + Foreign Sources (1000 lbs)	Total from Domestic Sources (1000 lbs)	Total from Foreign Sources ^a (1000 lbs)	Total from Exporting Countries with Phosalone Registered (1000 lbs)	Total from Exporting Countries without Phosalone Registered ^a (1000 lbs)	% from Countries with Phosalone Registered	% from Countries without Phosalone Registered
Almonds	nutmeat	532,714	532,600	114	1	113	0.0002 %	99.9998 %
Apples	fresh + dried	8,332,009	8,024,340	307,669	117,171	190,498	1.41 %	98.59 %
	juice	4,913,086	2,458,660	2,454,426	679,258	1,775,168	13.83 %	86.17 %
Apricots	fresh + dried + pulp/prepared or preserved + kernel (peach, plum or other stone fruits)	222,569	193,644	28,925	857	28,068	0.39 %	99.61 %
Cherries (Sweet & Tart Varieties)	fresh	184,006	172,384	11,622	938	10,684	0.51 %	99.49 %
Grapes	fresh + juice + wine	11,005,780	9,463,988	1,541,792	495,213	1,046,579	4.50 %	95.50 %
	raisins (fresh basis)	3,282,885	3,199,120	83,765	14,861	68,904	0.45 %	99.55 %
Peaches (including nectarines)	fresh	1,583,569	1,482,580	100,989	845	100,144	0.05 %	99.95 %
Pears	fresh (including quince) + nesoi	9,413,574	9,279,200	134,374	6,051	128,323	0.06 %	99.94 %
Plums	fresh + dried (fresh basis)	1,589,478	1,543,604	46,874	2,756	44,118	0.17 %	99.83 %

^a The values in these columns do not account for countries without phosalone registrations that are responsible for <1% of the corresponding commodity imported by the U.S.

Sample Calculations for the Case of Almonds

Given that

Total number of almond samples analyzed originating from exporting countries identified with phosalone registrations = 3 (Table 1)

Percent of almonds from countries with phosalone registered = 0.0002% (Table 2),

the following computation was performed to estimate the total number of almond samples representing both domestic and foreign sources:

Total number of almond samples representing both domestic and foreign sources = Total number of almond samples analyzed originating from exporting countries identified with phosalone registrations / Percent (as fraction) of almonds from countries with phosalone registered = $3 / 0.000002 = 1,500,000$.

The number of these almond samples with “non-zero” residues was interpreted to be equal to the number of field trials by assuming 100% crop treated in those countries exporting almonds to the U.S. that possess phosalone registrations. Of these “non-zeros,” one showed detectable residues of phosalone at 0.048 ppm. The remaining “non-zeros” were estimated to contain residues at $\frac{1}{2}$ LOD (limit of detection)=0.025 ppm². The number of almond samples with residues at $\frac{1}{2}$ LOD were found by subtracting the detectable residue from the total “non-zero” residues.

Number of “non-zeros” = 3

Number of “detects” = 1

Number at “ $\frac{1}{2}$ LOD” = 3 - 1 = 2

The number almond samples with “zero” residues was found by subtracting the number of “non-zeros” from the “total number of almond samples representing both domestic and foreign sources,” which was previously calculated:

Number of “zeros” = 1,500,000 - 3 = 1,499,997

The acute ARs for almonds was then expressed as distribution of the number of “non-zero,” “detect,” “ $\frac{1}{2}$ LOD,” and “zero” values in a Residue Distribution File (RDF).

The chronic ARs for almonds was calculated as follows:

Chronic Anticipated Residue = Sum of individual values of detectable residues, residues at $\frac{1}{2}$ LOD, and “zero” residues / Total sum of “non-zero” and “zero” residues = $[(0.048 + 0.025(2) + 0(1,499,997)] / (3 + 1,499,997) = 6.5 \times 10^{-8}$.

² The LOD (limit of detection) was interpreted to be equivalent to the LOQ (limit of quantitation). The LOQ=0.05 ppm for almonds. Hence, $\frac{1}{2}$ LOD = 0.025 ppm for almonds.

The acute and chronic ARs for almonds and the other crops/commodities are summarized in Table 3 for phosalone.

Table 3. Summary of Acute and Chronic ARs for Phosalone in/on Imported Fruits and Fruit Commodities

Crop	Commodity	Chronic AR, ppm ^a	Residue Distribution for Acute AR ^b
Almonds ^c	nutmeat	6.5e-08	0 (1,499,997), 0.025(2), 0.048
Apples ^d	fresh + dried	1.3e-04	0 (6,153), 0.0015 (83), 0.140, 0.200, 0.087, 0.060, 0.200
	juice	2.1e-04	0 (455), 0.0015 (73)
Apricots ^d	fresh	1.4e-05	0 (15,069), 0.0015 (58), 0.130
Cherries (Sweet & Tart)	fresh	1.6e-02	0 (2,341), 0.59, 0.38, 0.23, 0.35, 0.42, 0.25, 6.00 (6)
Grapes ^d	fresh + juice + wine	6.7e-05	0 (2,271), 0.0015 (107)
	raisins	5.8e-05	0 (8,185), 0.0015 (36), 0.420
Peaches ^d	fresh	1.8e-06	0 (117,941), 0.0015 (58), 0.130
Pears ^d	fresh	9.0e-07	0 (143,247), 0.0015 (86)
Plums ^d	fresh	6.2e-06	0 (34,647), 0.0015 (58), 0.130

^a Values in this column incorporate the percent imported from countries with phosalone registrations.

^b Residue values in this column also reflect the percent imported from countries with phosalone registrations. The frequency of the residue value is indicated in parentheses.

^c LOD equivalent to LOQ = 0.05 ppm; ½ LOD = 0.025 ppm. ½ LOD was used to represent almonds with non-detectable residues less than the LOD.

^d LOD equivalent to LOQ = 0.003 ppm; ½ LOD = 0.0015 ppm. ½ LOD was used to represent non-detectable residues less than the LOD for the indicated crops.

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